IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
Stewart A. Cederholm-Williams

Art Unit: 1632
Examiner: S.L. Chen

APPLICATION NO: 09/334,325

FILED: June 16, 1999

FOR: **FIBRIN SEALANT AS A TRANSFECTION/TRANSFORMATION VEHICLE**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY APPEAL BRIEF

Sir:

This is an appeal from the Final Rejection of claims 1 and 13-16.

REAL PARTY IN INTEREST

The real party in interest in this appeal is Bristol-Myers Squibb Company, a Delaware corporation, having a place of business at 345 Park Avenue, New York, NY 10154. Bristol-Myers Squibb Company is the assignee and owner of the entire interest in the above-identified application by virtue of an assignment which was recorded in the United States Patent and Trademark Office on August 23, 1999, at Reel/Frame 010191/0657.

RELATED APPEALS AND INTERFERENCES

The undersigned knows of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1 and 13-16 are pending in this application.

Claims 1 and 13-16 stand rejected under 35 USC §112, first paragraph, as allegedly lacking enablement.

No claims are allowed.

Appendix A annexed hereto contains a copy of the claims involved in the appeal. The appealed claims are claims 1 and 13-16.

STATUS OF AMENDMENTS

Appellant appeals the decision dated February 22, 2006, of the Primary Examiner finally rejecting claims 1 and 13-16. According to the Advisory Action mailed June 16, 2006, the amendment filed on April 21, 2006, after the final rejection has been entered. The amendment overcame the rejection under 35 USC § 112, second paragraph. Claims 1 and 13-16 remain pending in this application.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a method of transforming a cell comprising, in order, the steps of applying a transformation effective amount of a nucleic acid to the cell; adhering a pliable, adhesive fibrin gel to the cell so as to entrap a transformation effective amount of the nucleic acid in the fibrin gel adhered to the cell; and transforming the cell with the nucleic acid. See, for example, page 2, lines 9-17, of the specification.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue on appeal is whether claims 1 and 13-16 were properly rejected under 35 USC §112, first paragraph.

ARGUMENTS

I. Claims 1 and 13-16 were not properly rejected under 35 USC §112, first paragraph

Claims 1 and 13-16 stand rejected under 35 USC §112, 1st paragraph, as allegedly lacking enablement. Appellant requests that the rejection be reversed.

The issue presented in the rejection is whether Appellant has enabled the invention, however, Appellant submits that the basis of the rejection is an assertion that the application fails to demonstrate that the invention works. Thus, the 35 U.S.C. § 112 rejection is simply a rejection under 35 U.S.C. § 101 in the guise of a rejection under 35 U.S.C. § 112.

In any event, page 10 of the Office Action mailed on July 27, 2005, summarizes seven pages of rejection:

"The quantity of experimentation needed to make or use the present invention includes trial and error experimentation to **elucidate** the mechanism of cell transformation *in vitro* or *in vivo* by applying nucleic acid to cells first, then administering a pliable, adhesive fibrin gel to said cells, trial and error experimentation to determine how to **increase or enhance cell transformation efficiency** *in vitro* and *in vivo* by the claimed method, trial and error experimentation to determine how to administer a nucleic acid to the target cell on the surface of a subject or to the target cell at various locations inside the body of a subject, such as liver, kidney, lung, intestine, stomach, etc., trial and error experimentation to determine how to administer the pliable and adhesive fibrin gel to the target cell on the surface of a subject or to the target cell at various locations inside the body of a subject, such as liver, kidney, lung, intestine, stomach, etc., via various administration routes before the fibrin gel get polymerized so as to transform the target cell with said nucleic acid or to **increase cell transformation efficiency**, and trial and error experimentation to transform target cells with the claimed method such that therapeutic effects can be obtained for a particular disease or disorder *in vivo*" (emphasis added).

In a previous rejection, the Office acknowledged that transforming a cell *in vivo* was enabled when done with a stent or balloon catheter, and it was acknowledged in

another previous rejection that transforming a cell *in vitro* was enabled. The Office asked the applicant to explain or "elucidate" the mechanism of cell transformation. Appellant respectfully notes that even the most skilled in the art can offer no more than informed speculation on the mechanism of transformation and such is not a requirement of the patent law. That is, the patent law does not require an applicant to understand the theory of operation for his or her invention.

The rejection suggests that Appellant's invention must "increase or enhance cell transformation efficiency". That is not a requirement of the patent law either.

The rejection further indicates that Appellant must show every possible way to administer his invention. And that is not a requirement of the patent law.

Accordingly, Appellant submits that this rejection, whether under 35 U.S.C. §112 or §101, is without merit.

The current rejection suggests that the claims encompass transforming cells *in vivo* via various administration routes, such as intravenous and oral administration. However, the claims require applying a nucleic acid to a cell and adhering a gel to the cell so as to entrap the nucleic acid.

For all these reasons, it is submitted that this rejection should be withdrawn.

II. Conclusion

For the reasons set forth herein, it is urged that the rejection of claims 1 and 13-16 should be reversed. Allowance of this application with claims 1 and 13-16 is in order. Such action is earnestly solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method of transforming a cell comprising, in order, the steps of:

applying a transformation effective amount of a nucleic acid to the cell; and

adhering a pliable, adhesive fibrin gel to the cell so as to entrap the transformation effective amount of the nucleic acid in the fibrin gel adhered to the cell and thereby transforming the cell with the nucleic acid.

13. The method of claim 1, wherein the nucleic acid is a plasmid.

14. The method of claim 1, wherein the nucleic acid is incorporated in a virus.

15. The method of claim 1, wherein the pliable, adhesive fibrin gel is formed by mixing a fibrin monomer composition with a polymerizing agent preparation effective to convert the fibrin monomer preparation into a fibrin gel, and adhered by contacting the cell with the mixture while the mixture is pliable and adhesive.

16. The method of claim 15, wherein the fibrin monomer composition comprises acid-solubilized fibrin, and the polymerizing agent comprises an amount of base effective to sufficiently neutralize the mixture to allow the fibrin to polymerize.

EVIDENCE APPENDIX

NONE.

RELATED PROCEEDINGS APPENDIX

NONE.